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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,488	05/11/2006	Takuji Nishide	81844.0049	8234

26021 7590 12/22/2008

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,488	NISHIDE ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-15 and 17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-15, and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

The applicant has argued that Rowland (US 2007/0134290 A1) does not disclose the polymer/drug concentration claimed *per unit length*. It is the examiners position that due to fact that Rowland's total weight of polymer/drug applied to the stent (500ug disclosed in examples) is within the range of total weight of polymer/drug disclosed by the applicant (39ug-1040ug; see pages 20-21 of specification), Rowland inherently possesses the concentration per unit length. Since the stent used by the applicant is a standard sized stent (13 mm in length) and Rowland's invention is applicable to standard/common stents, Rowland's drug concentration would inherently fall within the claimed range. With a 13 mm commonly sized stent (length disclosed by applicant), Rowland's concentration per unit length would be 38ug/mm, which is right in the middle of applicants claimed range. In fact, the stent of Rowland would need to be of a length of anywhere between 6mm and 167mm in order to meet the claimed concentration per unit length (3-80ug/mm). Lengths of 6mm to 167mm are well within the standard sizes of stent use. See www.orbusmt.com/products/blazer/info/ordering which evidences the stent sizes available by the manufacturer of the Rowland publication (lengths of 9mm-33mm). Also provided as evidence showing standard stent sizes are Alt (US 6,398,805 B1; see col.8, lines 54-64 disclosing 8-9.5 and 15mm as standard) and Ryan (US 2002/0143392 A1; see P0014 disclosing standard lengths from 4mm-4cm). The use of Rowland's total polymer/drug weight (500ug) on standard sized stents provides the concentration required by the claim. If Rowland's polymer/drug concentration is not inherent (due to the standard stent size rationale), it would have been obvious to have such a concentration per unit length, since Rowland discloses varying the

amount of polymer/drug by adding additional layers or thickness, even varying where it is applied on the stent (P0036, P0043).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 does not further limit claim 8 (it instead broadens the concentration range).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 7-10, 12-15, and 17-19 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rowland et al. (US 2007/0134290 A1). Referring to claims 1, 7, 8, and 15, Rowland discloses a stent (fig.1; P0019) comprising an expandable tubular body (fig.1), the body containing a non-degradable material (metals, stainless steel, nitinol, etc. P0031) and a poly (lactide-co-glycolide) on a portion of the body's surface (P0034, P0035) and an immunosuppressive agent (P0044, claim 11) on the

surface. Rowland discloses the claimed weights of immunosuppressive and polymer (discloses 500ug in examples and figures, which falls within applicant claimed range; see applicant's specification, examples 16-19; further discloses 1-60% drug, thus 40-99% polymer, P0043). It is the examiners position that the concentration per unit length (claimed 3ug/mm-80ug/mm or 7ug/mm-65ug/mm) is inherent in Rowland since the total weight of polymer/drug disclosed by Rowland (500ug total weight) falls in the middle of the range disclosed by applicant (39ug-1040ug total weight). Also, applicant's polymer/drug is applied to a common sized stent (13mm). Rowland's polymer/drug matrix is applicable to common stents, thus when applied to a range of commonly sized (length) stents, Rowland has a concentration within the claimed range. The stent of Rowland would need to be of a length of anywhere between 6mm and 167mm in order to meet the claimed concentration per unit length (3-80ug/mm). Lengths of 6mm to 167mm are well within the standard sizes of stent use. See www.orbusmt.com/products/blazer/info/ordering which evidences the stent sizes available by the manufacturer of the Rowland publication (lengths of 9mm-33mm). Also provided as evidence showing standard stent sizes are Alt (US 6,398,805 B1; see col.8, lines 54-64 disclosing 8-9.5 and 15mm as standard) and Ryan (US 2002/0143392 A1; see P0014 disclosing standard lengths from 4mm-4cm). The use of Rowland's total polymer/drug weight (500ug) on standard sized stents provides the concentration required by the claim.

If not inherent that Rowland discloses the claimed concentration per unit length, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a concentration of 3ug/mm-80ug/mm since wherein the general conditions of a claim are disclosed in the prior art (polymer/drug matrix applied to the surface of a stent in some amount)

it is not inventive to discover the optimum or workable ranges through routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Rowland had disclosed 500ug total weight of polymer/drug as one example, however further discloses control over the amount of matrix by varying the thickness applied to the stent, the number of layers applied to the stent, and the amount of surface covered by the matrix (P0036, P0043). Thus other concentrations are envisioned and thus obvious over Rowland.

Regarding the dependent claims 2, 3, 5, 9-10, 12-14, and 17-19, Rowland discloses claimed polymer to cover the entire surface of the stent body (P0043). Rowland discloses the claimed molar ratios claimed (P0027, P0037). Rowland discloses the immunosuppressive agent to comprise tacrolimus, cyclosporine, sirolimus, azathioprine, or mycophenolate mofetil (P0044, claim 11). Rowland discloses mixing the layer or having separate layers of drugs and polymers with the possibility of multiple layers (P0043, P0020).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland et al. (US 2007/0134290 A1). Rowland discloses a stent substantially as claimed (see above). Rowland discloses a stent (fig.1) of a non-degradable material having a PLGA coating with an immunosuppressive agent. Rowland also discloses variation of the molecular weight of the

PLGA in order to optimize the degradation properties of the polymer (P0035, P0036, P0040). Rowland discloses the ability for the polymer to have low and high molecular weights (P0040), however is silent to mention any exact amounts (amount of 5000-13000 is claimed). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a poly (lactide-co-glycolide) with a molecular weight within the range claimed (5000-13000) since wherein the general conditions of a claim are disclosed in the prior art (variation of molecular weight) it is not inventive to discover the optimum or workable ranges. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738